

## **REMARKS**

The Official Action dated May 26, 2006 and the references cited therein have been carefully reviewed. In view of the amendments submitted herewith and the following remarks, favorable reconsideration and allowance of this application are respectfully requested.

At the outset, the Examiner indicates that claim 108 has been withdrawn from consideration for allegedly encompassing non-elected subject matter and claims 75 and 97 will only be examined to the extent that they read on the target gene being a plant viral gene. Additionally, the Examiner has indicated that claim 45 has been withdrawn from consideration. Accordingly, claims 33-36, 40, 41, 60-80 and 109-115 are currently being examined on the merits.

At page 3 of the Official Action, the Examiner has objected to the amendment filed on March 17, 2006 asserting that the amendment introduces new matter into the disclosure. Specifically, the Examiner contends that the phrase "corresponding complementary short sense RNA molecules" has no written support in the originally filed application.

The Examiner has maintained the rejection of claims 33, 35, 40, 41, 75, 77, 78, 93-110 and newly rejected claims 34, 36, 60-74, 76, 79, 80, 83 and 111-115 under 35 U.S.C. §112, second paragraph as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention.

Claims 33-36, 76 and claim 111 stand rejected under 35 U.S.C. §112, first paragraph as allegedly failing to comply with the enablement requirements of the statute.

The Examiner has rejected claims 33-36, 40, 41, 60-80, 83, 93-107 and 109-115 as allegedly lacking sufficient

written description in the specification.

At page 12 of the Official Action, the Examiner has rejected claims 33, 35, 40, 111 and 112 under 35 U.S.C. §102(b) as allegedly anticipated by Waterhouse et al. PNAS 95:13959-13964 (1998).

The Examiner has also rejected claims 33-36, 40, 41, 60-62, 64-75, 77-80, 83, 93-101 and 111-114 under 35 U.S.C. §102(e) as allegedly anticipated by the disclosure in US Patent 6,506,559 and "evidenced by Applicants admitted state of the prior art."

The foregoing objections and rejections constitute all of the grounds set forth in the May 26, 2006 Official Action for refusing the present application. Each of these objections and rejections are traversed for the reasons set forth below.

#### **BRIEF OVERVIEW OF THE INVENTION AND TEACHINGS IN THE SPECIFICATION**

Before responding to the various issues raised in the May 26, 2006 Official Action, Applicants wish to provide a brief overview of the invention disclosed in the present patent application.

The present inventors have described and claimed small RNA molecules of approximately 25 nucleotides which are the effectors of gene silencing. Three classes of RNA molecules are disclosed. These include single stranded antisense RNA molecules (SARMs), single stranded sense RNA molecules (SSRMs) and SRMs which contain both single stranded sense and antisense molecules. Throughout the specification, the inventors refer to a 25 nt species of RNA. The methods for purifying this species of RNA are provided at pages 6 and 7 of the specification. Notably,

this purification method will result in the obtention of SRMs as opposed to SARMs or SSRMs solely. Molecular characterization of these RNA molecules is provided in Example 1.

Example 1 describes silencing of the ACO gene in 5 lines of plants transformed with a cDNA encoding this enzyme. The identification of the 25 nt species as being of both sense and antisense polarity is based upon hybridization of labeled sense and antisense probes. At page 23, lines 29-33 these experiments are described as follows. "More specifically, the low molecular weight RNA and a 30 mer ACO antisense RNA oligonucleotide were fractionated, blotted and hybridized with either ACO sense RNA or antisense RNA transcribed from full length ACO cDNA." The results are discussed at page 23, lines 35-39 wherein the inventors disclose the following: "A discrete ACO antisense RNA of 25 nucleotides (nt) was present in both PTGS lines but absent from non-silenced lines. 25 ACO RNA of sense polarity and at the same abundance as the 25 ACO antisense RNA was also present only in the PTGS lines."

The silencing of PVX, GUS and GFP sequences were also correlated with the presence of this about 25 nt RNA species which was not detected in plants where silencing was not observed.

Having identified 25 nt RNA species of both sense and antisense orientation as the effector of gene silencing, the inventors sought to protect their invention via the filing of the present patent application. Once the 25 nt RNA species had been identified, it provided the common effector molecules that all in the field had been seeking, and made it a routine matter to then either sequence the isolated molecules or hybridize them to probes (either

sense or antisense as taught in Example 1) corresponding to known sequences in the target gene thereby generating the silencing agents encompassed by the claims. In a preferred embodiment, the silencing agent is an SRM comprising sense and antisense RNA molecules of approximately 25 nucleotides, at least one of which is complementary to the target gene. Given the disclosure in the present application, and the recognition by those skilled in the art of gene silencing that Drs. Baulcombe and Hamilton were responsible for this seminal contribution to the field (See results from Google Scholar Search, attached hereto), Applicants respectfully submit that they are entitled to patent protection for this invention and further that the present application complies with all statutory requirements for the same.

**THE AMENDMENT PRESENTED ON MARCH 17, 2006 DID NOT  
INTRODUCE NEW MATTER INTO THE DISCLOSURE**

In the May 26, 2006 Official Action, the Examiner contends that the phrase "corresponding complementary short sense RNA molecules" comprises new matter and requires Applicants to cancel this subject matter from the claims. Applicants respectfully disagree with the Examiner. As expressly stated in the specification, the SRMs of the invention comprise SARMs and SSRMs which are "short complementary molecules which could base pair with the target RNAs" (see page 2, lines 22-33). As the Examiner acknowledges the specification clearly discloses that antisense and "corresponding" sense strands were also detected. This language cannot be considered new matter as

*ipsisimous verbis* support for these claim limitations is found in the present specification. Inasmuch as the claims have been amended to recite that which is literally disclosed in the specification, this objection cannot stand. Accordingly, Applicants submit that the objection to the specification has been overcome.

**THE METES AND BOUNDS OF THE CLAIMS AS AMENDED ARE  
CLEAR TO ONE OF ORDINARY SKILL IN THE ART**

The Examiner has maintained the rejection of claims 33, 35, 40, 41, 75, 77, 78 and 93-110 and newly rejected claims 34, 36, 60-74, 76, 79, 80, 83 and 111-115 as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter regarded as the invention. The claims have been amended to clarify the allegedly unclear subject matter.

The Examiner continues to contend that claims 33 and 40 are indefinite for inclusion of the phrase "silencing agent" and further asserts "it remains unclear what else a silencing agent can be if it is not an SRM." Claims 33 and 40 clearly state that the silencing agent comprises an SRM consisting of SARMS which can hybridize to sense strands of the target gene and SSRMs which can hybridize to antisense strands of the target gene and dependent claim 111 recites that these molecules are present in equal abundance. Thus, Applicants submit that the skilled artisan would readily be apprised of the metes and bounds of these claims. Literal support for this amendment to claim 33 can be found in Example 1, at page 23, line 35. Additionally, Claim 35 has been cancelled thereby rendering the rejection of this claim moot.

As set forth in Applicants' previous response, the

SRMs are RNAs which are "short complementary molecules which could base pair with the target RNAs" (see page 2, lines 28-33). In light of the definition of SRMs provided in the specification, and the biochemical characterization of the molecules via hybridization studies using sense and antisense probes corresponding to sequences from the target gene, it is respectfully submitted that the metes and bounds of the recitation of "silencing agent" would be clear to one of skill in the art. Reconsideration and withdrawal of this ground of rejection is therefore, respectfully requested.

As a final note in this regard, Applicants take exception to the Examiner's characterization of SRMs as "an individual nucleic acid molecule" as stated at the top of page 5 of the Official Action. As the Examiner acknowledges Applicants have defined SRMs as collectively referring to **BOTH** sense and antisense RNAs of approximately 25 nt. Moreover, it is conventionally understood by the skilled person that when one refers to molecules which are sense and anti-sense to a single target sequence, such molecules, or at the very least a sub population of such molecules, readily hybridize with one another and hence are complementary to each other. Explicit support and disclosure is found in the specification as filed stating that the nature of the SRMS is that they are short complementary molecules which could hybridize with a target gene. The short antisense RNA effector molecules are noted as being accompanied by corresponding sense RNA molecules. In light of this explicit teaching, it is urged that it is incumbent on the Examiner to provide specific evidence to contradict Applicants' interpretation of the disclosure. The Examiner has provided no evidence whatsoever

contradicting this teaching in the specification. The further assertion that there is no indication that SRMs can be interpreted to read on double stranded molecules is also in error. The disclosure expressly teaches at page 3, lines 10-26 that PTGS in plants and dsRNA interference in nematodes are similar, if not identical processes. The distinction here being that, for the first time, the Applicants demonstrated that the effector molecules common to PTGS in plants, nematodes and higher organisms are short complementary sense and corresponding antisense RNA molecules (i.e. SRMs).

At page 6 of the Official Action, the Examiner asks the question: "If a SRM is a double stranded molecule, why would the specification teach that either a SARM or a SSRM could be used." As mentioned above, the specification as originally filed discloses three classes of molecules, single stranded antisense molecules, single stranded sense molecules and SRMs which comprise both antisense and sense molecules. It is a well-settled premise in patent law that an inventor need not know exactly how his invention works mechanistically. See Parker v. Frilette, 174 U.S.P.Q 321,324 (CCPA 1972) ("[an] inventor need not understand precisely why his invention works in order to achieve an actual reduction to practice"). Applicants respectfully submit that the molecular mechanism underlying gene silencing is still a very active area of research 7 years after the filing date of the present application. Nonetheless, it is widely accepted in the art that short double stranded molecules when present in a cell are effectors of PTGS, regardless of the mechanism by which their effect is achieved.

Briefly, as it is currently understood, gene silencing

involves a complex of proteins and enzymes, known as the RNA Induced Silencing Complex, or "RISC" which binds to one of the strands of a short RNA duplex and utilizes that strand to guide sequence specific cleavage of a target RNA molecule. Notably, this guiding molecule, which is incorporated in the RISC can base pair with the target gene. Short single stranded RNA molecules (e.g., SARMs) may be taken up by a RISC complex to effect cleavage of a target RNA, but the efficiency of this process is much lower than when a short double stranded RNA is present for take-up by or assembly into the RISC complex. See Martinez et al., Cell 110:563-574, (2002; submitted with the response to the previous Official Action) who showed that short dsRNA reconstitutes RISC at a concentration that is about 10 to 100 fold lower than that required for a short single stranded RNA.

It cannot be questioned that both sense and antisense short RNA molecules are encompassed by the definition of SRMs (i.e., silencing agents) utilized in the specification and in the present claims. This is further made explicit by the statement in the first paragraph of the Disclosure of the Invention, which states that where short antisense RNA molecules complementary to the targeted mRNA were detected, "Corresponding sense RNA molecules were also detected." Again, these short RNA molecules are sense and antisense to a single target gene, and are explicitly taught in the specification to be complementary molecules.

The claims as originally filed also clearly encompass three classes of molecules, SRMS (which are collectively SSRMs and SARMs), SARMs and SSRMs. See original claims 1, 5, 6 and 26 which are reproduced below. Applicants contemplated and described three different classes of



molecules which are effective to silence a target gene. Applicants' presentation of original claims 5 and 6 clearly support this position. If the SSRMs, SARMs and SRMs were identical, these claims would fail to further limit the subject matter of claim 1. Nor would claim 26 have been drafted to clearly indicate that the silencing agent may be **either** one or more SRMs **OR** an antisense molecule which can target a target gene.

**ORIGINALLY FILED CLAIMS:**

Original Claim 1. A method of screening for the occurrence of gene silencing in an organism, which method comprises the steps of

- (i) obtaining a sample of material from said organism,
- (ii) producing a nucleic acid extract from said sample,
- (iii) analysing said extract such as to determine the presence or absence of short RNA molecules which are approximately 25 nucleotides in length(SRMs) in said nucleic extract, and
- (iv) correlating the presence of said SRMs in the extract with the occurrence of gene silencing in said organism.

Original Claim 5. The method in accordance with claim 1, wherein the SRMs are short anti-sense RNA molecules (SARMs).

Original Claim 6. The method in accordance with claim 1, wherein the SRMs are short sense RNA molecules (SSRMs).

Original Claim 26. A DNA construct in which a promoter is operably linked to DNA for transcription in a host cell to generate a silencing agent for a target gene being selected from either:

- (i) one or more SRMs, or
- (ii) an anti-sense RNA molecule capable of targeting a region of said target gene selected in accordance with the method of claim 18.

It is further noted, in this context, that issued patent no. 6,753,139, which granted from a common parent to the instant application, includes claims 1, 2, and 3, as

follows:

1. A method of detecting the silencing of a target gene in a plant, wherein said silencing is initiated by introduction of an exogenous nucleic acid, which method comprises the steps of:

- (i) obtaining a sample of material from said plant,
- (ii) producing a nucleic acid extract from said sample,
- (iii) analyzing said extract such as to determine the presence or absence of short RNA molecules which are 21-25 nucleotides in length (SRMs) in said extract,
- (iv) characterizing any SRMs which are present in said extract such as to determine sequence identity or similarity with said target gene, and
- (v) correlating the presence of said SRMs having sequence identity or similarity with said target gene in the extract with the occurrence of gene silencing in said plant.

2. A method in accordance with claim 1 wherein the SRMs are short anti-sense RNA molecules (SARMs).

3. A method in accordance with claim 1 wherein the SRMs are short sense RNA molecules (SSRMs).

Clearly, therefore, the term SRMs encompasses short anti-sense RNA molecules AND short sense RNA molecules, and this is a point that the USPTO has already conceded.

While different embodiments of the invention are described in the specification, the present claims are directed to methods for silencing a gene in an organism via the introduction of a silencing agent consisting of SRMs into a cell expressing the target gene to be silenced. Applicants note that it is wholly improper for the Examiner to seek to limit Applicants to certain embodiments of the invention when explicit disclosure consistent with a broader interpretation, or an interpretation that more closely reflects the subject matter the inventors regard as their invention is provided in the specification and in the original claims as filed. Additionally, Applicants reserve the right to file one or more continuing applications on these additional embodiments.

The Examiner also contends at page 6 that it is not

clear how sense and antisense sequences can both be complementary to the same sequence. The qualification in the disclosure at page 2 that SRMs are short complementary molecules "which could base pair with the target RNAs" does not **require**, as the Examiner asserts, that the short complementary molecules both base pair with the target RNAs, or that they base pair with the target RNAs while in a double stranded form. Indeed, "could" which is the past tense of "can" is defined as 1: ability; 2: Possession of a specified power, right or means; i.e., the term is employed to indicate an ability to do something, not the requirement that the thing be done. The short sense RNA of the SRMs could base pair with the antisense strand of the gene, while the short antisense RNA molecule of the SRMs could base pair with the mRNA or sense strand of the gene. In fact, as mentioned above, it has been confirmed in the literature that short double stranded RNA molecules which comprise antisense strands that could base pair with a target molecule, in fact enter the RISC complex described above wherein the short antisense RNA strand is stripped from its complement, and is utilized by the RISC to cleave the target RNA. This point is further emphasized in the specification which does not exclude the use of such short single stranded RNA, for example short single stranded antisense RNA or SARM. In this embodiment of the invention, if single stranded RNA is being utilized, it is preferable to use a SARM as opposed to a short sense RNA, e.g., a SSRNA, to induce silencing (something that has since been confirmed to occur). The SRMs presently being claimed represent an alternative embodiment of this invention.

Claim 60 has been amended to reflect the claim amendments to claims 33 and 40 and to further clarify that

it is the SARM component of the SRM which binds to the mRNA of the target gene. Claims 77, 100 and 109 have been cancelled. Claims 93 and 102 have also been amended to further clarify the subject matter encompassed by these claims.

At page 6 of the Official Action, the Examiner has rejected claims 33 for lacking proper antecedent basis for the recitation of the targeted region in the last line. The claim has been amended to remove the phrase lacking proper antecedent basis, thereby rendering this rejection moot. Claims 33, 40, 60, 93 and 102 are allegedly unclear for inclusion of the phrase "corresponding complementary". Applicants again reiterate that the present inventors have expressly described an about 25 nt RNA population comprising both sense and antisense molecules which, when present, effectively silence a target gene. The skilled person would readily appreciate that the phrase "corresponding complementary" sense molecules refers to those molecules which could hybridize to antisense molecules of the same target. Accordingly, it is submitted that the metes and bounds of the phrase are clear.

Claims 75 and 97 have been amended to provide proper antecedent basis for the features recited therein.

In light of all the foregoing, it is respectfully submitted that the claims are amended fully comply with the requirements of 35 U.S.C. §112, second paragraph. Accordingly, the rejection of claims 33-36, 40, 41, 60-80, 83, 93-110, and 111-115 is improper and should be withdrawn.

**THE CLAIMS AS AMENDED FULLY COMPLY WITH THE ENABLEMENT  
REQUIREMENTS UNDER 35 U.S.C. §112, FIRST PARAGRAPH**

Claims 33-36, 76 and 111 remain rejected as allegedly encompassing subject matter which was not enabled by the disclosure in the specification. Claims 35 and 36 have been cancelled, rendering the rejection of these claims moot.

The Examiner contends that the practice of the method of claim 76 requires undue experimentation as Applicants have not provided the "gene sequence of all plant parasite-resistance conferring genes and the parasites that each of these genes confers resistance against". In response, Applicants submit that a variety of plant resistance gene encoding sequences **WERE** known in the art at the time the present application was filed. Moreover, it is a well settled premise in patent law that a patent need not teach, and preferably omits, what is well known in the art.

Lindemann Maschinenfabrik v. American Hoist and Derrick, 221 USPQ 481, 489 (Fed. Cir. 1984). Should the Examiner maintain the rejection of claim 76, Applicants stand ready to submit the gene sequences of parasite resistance conferring genes that were known to the skilled person as of the filing date of the present application.

The Examiner has rejected claim 33 for the recitation that the silencing agent base pairs with the target gene. At page 8 of the Official Action, the Examiner asserts, "However, neither the specification nor the prior art teach that PTGS occurs by base pairing of a nucleic acid with a gene within the genome of a plant cell or how a double stranded nucleic acid molecule can base pair with another nucleic acid molecule". In response, the Examiner is reminded that an inventor need not appreciate the molecular

mechanism underlying his invention, he need only teach the skilled person how to make and use the invention. The explicit disclosure of an about 25 nt RNA species comprised of sense and antisense molecules which could hybridize with sense and antisense strands of a target is consistent with the currently understood mechanism by which silencing utilizing short double stranded RNA effector molecules in fact occurs.

Applicants are unclear as to the nature of the enablement rejection of claim 111. This claim was not included in the previous rejection under 35 U.S.C. §112, first paragraph. Applicants respectfully request that the Examiner provide the reasoning for the rejection of this claim in the next Official Action.

In light of the foregoing remarks and claim amendments, the rejection of claims 33-36, 76 and 111 under 35 U.S.C. §112, first paragraph is untenable and should be withdrawn.

**CLAIMS 33-36, 40, 41, 60-80, 83, 93-107, AND 109-115 AS  
AMENDED FULLY COMPLY WITH THE WRITTEN DESCRIPTION  
REQUIREMENT OF 35 U.S.C. §112, FIRST PARAGRAPH**

The Examiner has rejected the aforementioned claims asserting that the subject matter encompassed thereby was not described in such a way as to convey to the skilled person that the present inventors were in possession of the invention at the time the present application was filed. Applicants respectfully disagree.

As mentioned above in connection with the rejection of the claims under 35 U.S.C. §112, second paragraph, the present specification discloses three distinct classes of molecules, i.e., SRMs which comprise **BOTH** SARMs and SSRMs,

SARMS and SSRMs. The Examiner's assertion that "There is no written descriptive support for the recitation "short RNA molecules comprising SARMS and corresponding complementary SSRMs in the original application" is flatly contradicted by the disclosure in the application. While the Examiner appears to acknowledge the disclosure at page 2 of the application, he further contends that the term collectively is not synonymous with complementary. In response, it is noted that the specification explicitly states the nature of the SRMS, i.e., short complementary RNA molecules which could hybridize with a target mRNA. Accordingly, whether corresponding does or does not mean that the sense and antisense short RNA molecules are complementary is not worth debating. The specification is explicit on this point. The Examiner has provided no evidence whatsoever to refute this explicit disclosure found in the application. At page 9 of the previous Official Action, the Examiner stated the following: *"...the specification while being enabling for the claimed method when the nucleic acid sequence that is introduced into the cell to cause PTGS is double stranded, or if singled stranded, is not as small as 30 nucleotides, does not reasonably provide enablement for the claimed method with single stranded SRMs."* Applicants assert that this statement does indicate that the Examiner previously acknowledged that the instant specification enables methods using double stranded SRMs as this is a direct quote from the Action.

At pages 11 and 12 of the present Official Action the Examiner emphasizes the disclosure relating the SARM aspect of the invention, yet ignores other sections of the disclosure which clearly state that SRMS comprise **BOTH**

SARMS and SSRMS. Moreover, the data presented in Example 1 clearly indicates that the 25 nt species are of sense and antisense polarity with respect to the target gene. The contention that they could therefore, form double stranded RNA logically follows.

Regarding the rejection of claims 75 and 97, the Examiner contends that the recitation "contained within said cell" is not supported by the disclosure in the specification. The Examiner's attention is respectfully drawn to page 25 of the specification wherein the 25 nt RNA species was isolated following synchronized PVX infection on leaves of untransformed *N. bethamiana*. Thus, the virus infected these cells and its expression was silenced by the 25 nt RNA silencing agent present therein. Accordingly, Applicants submit the Examiner's contention is in error.

The present claim amendments are all explicitly supported by the disclosure in the present application. It is without question that the present inventors were in possession of the methods presently claimed as of the filing date of this application. In light of the foregoing remarks and claim amendments, Applicants request that the rejection of the claims for allegedly lacking an adequate written description and containing new matter be withdrawn.

**THE CLAIMS AS AMENDED ARE NOVEL OVER WATERHOUSE ET AL. AND  
FIRE ET AL.**

The Examiner contends that the disclosure in Waterhouse et al. anticipates the subject matter of claims 33, 35, 40, 111 and 112. Applicants respectfully disagree. In order to render claims lacking in novelty, a prior art reference relied on in a §102 rejection must identically disclose each and every element claimed. It is



respectfully submitted that claims as amended are novel over Waterhouse et al.

Claim 33 as amended recites a method of silencing a target gene in an organism by post-transcriptional gene silencing (PTGS), the method comprising the step of introducing into the organism a silencing agent comprising SRMs consisting of SARMs which hybridize to sense strands of the target gene and SSRMs which hybridize to antisense strands of the target gene, each of said SARMs and SSRMs being 25 nucleotides (25nt) in length minus 1, 2, 3, 4 or 5 nucleotides, and being effective to silence the target gene when present in a cell expressing said target gene. The other independent claims have been amended in a comparable fashion. The constructs disclosed by Waterhouse et al. contained the entire open reading frame of Pro in a sense or antisense orientation as well as a construct containing a stop codon within three codons of the initiation codon. Accordingly, inasmuch as this reference does not describe short complementary RNA molecules, it cannot disclose a method which identical to that presently claimed. Therefore, the anticipation rejection of claims 33, 35, 40, 111 and 112 based on this reference is inappropriate and should be withdrawn.

The Examiner has rejected claims 33-36, 40, 41, 60-62, 64-75, 77-80, 83, 93-101, and 111-114 as allegedly anticipated by the disclosure in US Patent 6,506,559 to Fire et al.

It is the Examiner's position that "Fire et al (U.S. 6,506,559) teach dsRNA that is at least 25 bases in length that is complementary to a target gene and silences the target gene's expression when in a cell (see column 8). Therefore, the dsRNA molecules taught by Fire et al. would

meet the instant limitation of 25 nucleotides minus 1, 2, 3, 4 or 5 nucleotides in length. Accordingly, the instant invention is anticipated by Fire et al."

Notably, claim 33 and the other independent claims have been amended to recite SRMs which are 25 minus 1, 2, 3, 4, 5 nucleotides in length. A careful reading of Fire et al. reveals that the constructs exemplified typically contained hundreds of nucleotides, and none are about 25 or less in length (See Figure 4).

At Column 3 over to Column 4 of Fire et al., those inventors disclose: "The transgene-mediated genetic interference phenomenon called co-suppression may include a wide variety of different processes. From the viewpoint of application to other types of organisms, the co-suppression phenomenon in plants is difficult to extend...The lack of a predictable effect in plants, nematodes, and insects greatly limits the usefulness of simply adding transgenes to the genome to interfere with gene expression. Viral-mediated co-suppression in plants appears to be quite effective, but has a number of drawbacks. First, it is not clear what aspects of the viral structure are critical for the observed interference. Extension to another system would require discovery of a virus in that system which would have these properties, and such a library of useful viral agents are not available for many organisms. Second, the use of a replicating virus within an organism to effect genetic changes (e.g., long- or short-term gene therapy) requires considerably more monitoring and oversight for deleterious effects than the use of a defined nucleic acid as in the present invention."

This disclosure in Fire clearly demonstrates that Fire et al. were not in possession of the invention as currently

claimed. Additionally, in order to expedite prosecution of the present application, the claims have been amended to recite silencing agents which consist of SRMS which are 25 minus, 1, 2, 3, 4 or 5 nucleotides. The skilled person reading Fire would not envision that the SRMs encompassed by claim 33 would be effective to silence target genes in a wide variety of organisms. It is well settled that prior art under 35 U.S.C. §102 must sufficiently describe the claimed invention to have placed the public in possession of it. In re Sasse, 207 U.S.P. Q. 107, 11 (CCPA 1980). Such possession is established if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. See In re LeGrice, 133 U.S.P.Q. 365, 371 (CCPA 1962). Accordingly, even if the claimed invention were arguably disclosed in a printed publication, that disclosure would not suffice as prior art if it were not enabling. In re Borst, 45 U.S.P.Q. 554, 557 (CCPA, 1965). In re Donohue, 226 USPQ 619, 621 (Fed. Cir. 1985). In re Hughes, 145 U.S.P.Q. 467 (CCPA 1965) stands for the premise that words in a reference are construed in light of the relevant surrounding circumstances in each case. A reference is only good for what it clearly and definitely discloses. An ambiguous reference **will not support** an anticipation rejection.

Clearly, the skilled person, reading the foregoing disclosure in Fire, coupled with the exemplification of dsRNA encoding constructs of several hundred nucleotides in length would not conclude that Fire et al. were in possession of the methods of inducing gene silencing using the SRMs encompassed by claims, 33, 40, 60, and 93. Moreover, it cannot be reasonably maintained that Fire et

al. disclose an identical method in light of the present claim amendments. Accordingly, Applicants' request that this rejection be withdrawn.

#### CONCLUSION

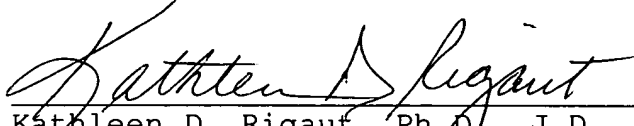
It is respectfully requested that the amendments presented herewith be entered in this application, since the amendments are primarily formal, rather than substantive in nature. This amendment is believed to clearly place the pending claims in condition for allowance. In any event, the claims as presently amended are believed to eliminate certain issues and better define other issues which would be raised on appeal, should an appeal be necessary in this case.

In view of the amendments presented herewith, and the foregoing remarks, it is respectfully urged that the rejections set forth in the May 26, 2006 Official Action be withdrawn and that this application be passed to issue.

In the event the Examiner is not persuaded as to the allowability of any claim, and it appears that any outstanding issues may be resolved through a telephone or in-person interview, the Examiner is requested to call the undersigned at the phone number given below.

Respectfully submitted,  
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### A Species of Small Antisense RNA in Posttranscriptional Gene Silencing in Plants

AJ Hamilton, DC Baulcombe - *Science*, 1999 - dx.doi.org

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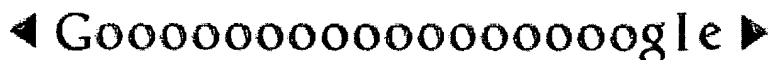
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